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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,674	07/17/2003	Toby Freyman	10177-166-999	3657

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222 EAST 41ST ST
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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,674	FREYMAN, TOBY	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *8-11 and 26-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12-25,50-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/05;3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1 – 7, 12 – 25 and 50 – 65 and species election VEGF, in the reply filed on February 6, 2006 is acknowledged. The traversal is on the ground(s) that the inventions are related and connected such that the searches are the same, thus no burden exists to search the groups together. This is not found persuasive because while the groups are related and the searches would be overlapping, an overlapping search is not a coextensive search. Thus a reference that would anticipate one group may not anticipate or even make obvious another group.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8 – 11 and 26 – 49 are withdrawn as being drawn to non-elected subject matter. Claims 1 – 7, 12 – 25 and 50 – 65 have been considered on the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 – 6, 12 – 22, 24 – 25, 50 – 60, and 64 – 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Abatangelo (WO 97/188420.

Applicant claims a composition comprising decellularized bone marrow extracellular matrix, wherein the bone marrow extracellular matrix has been produced in vivo in an animal. The animal is a mammal selected from a cow, pig, horse, chicken, cat dogy, rat, monkey or human; the human is an adult, adolescent, neonate or fetus; the extracellular matrix is arranged in a structure wherein the structure is maintained after the bones marrow is decellularized and the composition further comprises a biological material in the form of a scaffold, and is suitable for implantation.

Abatangelo teaches a biological material comprising extracellular bone marrow free of cellular components (or decellularized) and its use in tissue grafts (or are combined with biological materials) (abstract).

The reference does not teach the method by which the compositions are produced. However, these claims are considered to be product by process claims. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

4. Claims1 – 5, 12 – 21, 24 – 25, 50 – 59 and 62 – 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (1999) or Peters (1993).

Applicant claims a composition comprising decellularized bone marrow extracellular matrix, wherein the bone marrow extracellular matrix has been produced in vivo in an animal. The animal is a mammal selected from a cow, pig, horse, chicken, cat dogy, rat, monkey or human; the human is an adult, adolescent, neonate or fetus; the extracellular matrix is arranged in a structure wherein the structure is maintained after the bones marrow is decellularized

Lee et al. (1999) teaches a composition comprising decellularized bone marrow from fetal bovines (p.301)

Peters et al. (1993) teaches a composition comprising decellularized bone marrow and(p.286).

The references do not teach the method by which the compositions are produced. However, these claims are considered to be product by process claims. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1 – 7, 12 – 25 and 50 – 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abatangelo in view of Cobb et al. (US 6241981).

Applicant claims a composition comprising decellularized bone marrow extracellular matrix, wherein the bone marrow extracellular matrix has been produced in vivo in an animal. The animal is a mammal selected from a cow, pig, horse, chicken, cat dogy, rat, monkey or human; the human is an adult, adolescent, neonate or fetus. The extracellular matrix is arranged in a structure wherein the structure is maintained after the bones marrow is decellularized; further comprises a biological material that is VEGF. Applicant claims a biocompatible material comprising decellularized bone marrow extracellular matrix wherein the bone marrow extracellular matrix has been produced in vivo in an animal, produced by a claimed method. The biocompatible material is a scaffold and is suitable for implantation into a patient.

Abatangelo teaches a biological material comprising extracellular bone marrow free of cellular components (or decellularized) and its use in tissue grafts (or are combined with biological materials) (abstract).

Abatangelo does not teach the composition further comprising VEGF. However, the reference does teach the composition for use in tissue grafts. At the time of the claimed invention, VEGF was known and used in the art with tissue grafts. In support, Cobb teaches tissue grafts in combination with VEGF (col.4). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine VEGF with the

decellularized bone marrow of Abatangelo with a reasonable expectation for successfully obtaining the composition of Abatangelo.

The reference does not teach the method by which the compositions are produced. However, these claims are considered to be product by process claims. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 31, 2006
AU 1651

RUTH A. DAVIS
PATENT EXAMINER